

REMARKS/ARGUMENTS

Claims 1-17 are pending in this application, of which claims 1-4, 6-7, 9-10, and 12-17 have been withdrawn from consideration. By this Amendment, claims 5 and 11 have been amended. No new matter has been added.

Claims 5, 8, and 11 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The examiner argued that the application does not sufficiently describe the invention as it relates to all possible diagnoses of diseases associated with protein depositions that are compatible with the instant invention. Accordingly, claim 11 has been amended to recite "detection of amyloid plaques." In addition, the Examiner argues that the formula as set forth in claim 5 does not adequately describe the variables Y and Rph. The current amendment has been rewritten to replace a description of variables X and Y with a definition of X-Y as representing O-H, S-H, =O or a carbohydrate radical; and to replace a description of Rph with a description of a phenol group, said phenol group being optionally substituted by a radioactive isotope other than I¹²⁵, a halogen, H or a radical optionally having a radioactive isotope other than I¹²⁵. Accordingly, withdrawal of the rejection of claims 5, 8, and 11 under 35 U.S.C. 112, first paragraph, is respectfully requested.

Claims 5, 8, and 11 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the sUbject matter which applicant regards as the invention. The Examiner argued that

independent claim 5 is vague and indefinite. Specifically, in line 6, the phrase 'Y represents H or, along with X where X = O, a carbohydrate' is confusing. It is believed that replacement of the description of variables X and Y with a definition of X-Y as representing O-H, S-H, =O or a carbohydrate radical, as discussed above, clarifies this issue. Additionally, in lines 22-25, the claim is confusing because of the phrase 'Rph... group;'. Specifically, the phrase is confusing because there is no Rph variable in the structure or variable definitions. Again, it is believed that replacement of the description of Rph with a description of a phenol group, as discussed above, clarifies this issue. Finally, in lines 28-29, the claim is confusing because the variable X cannot be hydrogen. (d) In lines 30-31, the claim is confusing because the variables X and Y cannot be or contain a radioisotope. Identification of X as possibly being hydrogen and of X and Y as possibly being or containing a radioisotope has been deleted.

The Examiner argued that claim 11 as written is ambiguous because it is unclear for what diagnosis of diseases associated with protein deposition Applicant is claiming that are compatible with the instant invention. Therefore, claim 11 has been amended to recite "detection of amyloid plaques."

Accordingly, withdrawal of the rejection of claims 5, 8, and 11 under 35 U.S.C. 112, second paragraph, is respectfully requested.

Claims 5 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Lamberg et al (Nuklearmedizin, 1967, Vol. 6, No.1, pp. 16-19). Lamberg et al

disclose ^{125}I -labeled iodochloroxyquinoline which fulfills the requirement of the originally claimed invention when Y = hydrogen; X = oxygen; A = nitrogen; m = 1; n = 1; p = 1; B = CR₅; D = CR₆; E = CR₇ ; R₅ = hydrogen; R₆ = hydrogen; R₇ = hydrogen; R₁ = 125-iodine; R₂ = hydrogen; and R₃ = chlorine. However, claim 5 has been amended to exclude the presence of ^{125}I as a radioisotope.

Additionally, claim 11 recites a pharmaceutical composition for detection of amyloid plaques in the central nervous system. Lamberg does not disclose or suggest a pharmaceutical composition for detection of amyloid plaques in the central nervous system. Further, Lamberg does not disclose or suggest a pharmaceutical composition having any utility in the central nervous system. Lamberg teaches a composition for use in the thyroid gland. The Examiner admits that the cited prior art does not disclose the particular use (Page 10 of the Office Action).

Accordingly, withdrawal of the rejection of claims 5 and 11 under 35 U.S.C. 102(b) is respectfully requested.

Claims 5, 8, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lamberg et al (Nuklearmedizin, 1967, Vol. 6, No.1, pp. 16-19) in view of Wilbur et al (US Patent No. 4,885,153) or in view of Baldwin et al (US Patent No. 4,279,887). Lamberg et al disclose ^{125}I -labeled iodochloroxyquinoline. However, while Lamberg et al disclose a radioactive iodochloroxyquinoline compound, the

reference fails to disclose other possible isotopes of iodine that may be used with the structure.

Wilbur et al discloses that it is known in the art to replace any radioisotope of iodine (i.e., 123-iodine, 125-iodine, or 131-iodine) with another (column 3, lines 43-53). Baldwin et al disclose that it is known in the art to replace any radioisotope of iodine (i.e., 123-iodine, 125-iodine, or 131-iodine) with another (column 2, lines 64-67).

The Examiner argues that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Lamberg et al using the teachings of Wilbur et al and Baldwin et al and replace the 125-iodine substituent with 123-iodine because the cited secondary references each disclose that 125-iodine and 123-iodine may be used interchangeably. However, the prior art does not support the contention that 125-iodine and 123-iodine may be freely interchanged in a pharmaceutical. Lamberg uses 125-iodine only in laboratory research in a rat, but not in testing of a pharmaceutical. Wilbur clearly indicates that specific iodine isotopes are preferred for specific applications: "Preferred radiohalogens *X for diagnostic imaging purposes include I-131 and *most preferably I-123 for imaging with gamma cameras*; and for positron tomographic imaging: R-18, Br-75, and Br-76. For clinical radiotherapy, preferred radiohalogens *X include I-131, Br-77, and At-211. *Preferred radiohalogens *X for in vitro radioimmunoassay purposes include I-125 and I-131.*" Wilbur, Col. 3, lines 43-57, *emphasis added*. The

preference for I-123 for imaging is due to its short half-life of about 13 hours. I-125, which has a half-life of around 60 days, is a radioisotope of iodine which has uses in biological assays, as described by Wilbur, and in radiation therapy to treat prostate cancer and brain tumors. I-123, with its short half-life, would have been unsuitable for use by Lamberg since Lamberg required the species to persist in an animal after administration of the drug for at least 72 hours before sacrifice and testing. *Lamberg, page 16, Materials and Methods.* It would not have been obvious to a person of ordinary skill in the art to interchange I-123 and I-125, since the isotopes have different half-lives which render them suitable for different purposes.

Additionally, claim 11 recites a pharmaceutical composition for detection of amyloid plaques in the central nervous system. Lamberg does not disclose or suggest a pharmaceutical composition for detection of amyloid plaques in the central nervous system. Further, Lamberg does not disclose or suggest a pharmaceutical composition having any utility in the central nervous system. Lamberg teaches a composition for use in the thyroid gland. The Examiner admits that the cited prior art does not disclose the particular use (Page 10 of the Office Action), but argues that the compound/composition would be capable of having the same use as Applicant's invention since a product and its properties are inseparable. In point of fact, absent the teachings in the current disclosure, a person of ordinary skill in the art would have no motivation to use the composition of Lamberg for imaging the central nervous system, particularly since the

radionuclide used by Lamberg is a long half-life radionuclide used pharmaceutically primarily for radiation therapy. Since the pharmaceutical utility of the composition of claim 11 is not derivable from the prior art of record, the Examiner's assertion that the compound/composition of Lamberg has the same use as Applicant's invention can only be viewed as improper hindsight reconstruction from Lamberg in view of the statement of the problem to be solved as set forth in the current application.

Accordingly, withdrawal of the rejection of claims 5, 8, and 11 under 35 U.S.C. 102(b) is respectfully requested.

CONCLUSION


While we believe that the instant amendment places the application in condition for allowance, should the Examiner have any further comments or suggestions, it is respectfully requested that the Examiner telephone the undersigned attorney in order to expeditiously resolve any outstanding issues.

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Respectfully submitted,
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